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PP RUEHWEB

DE RUEHSG #2303/01 3071214
ZNR UUUUU ZZH
P 031214Z NOV 06
FM AMEMBASSY SANTIAGO
TO RUEHC/SECSTATE WASHDC PRIORITY 0306
INFO RUEHAC/AMEMBASSY ASUNCION PRIORITY 2714
RUEHBR/AMEMBASSY BRASILIA PRIORITY 3376
RUEHBU/AMEMBASSY BUENOS AIRES PRIORITY 3290
RUEHCV/AMEMBASSY CARACAS PRIORITY 1162
RUEHLP/AMEMBASSY LA PAZ NOV 4876
RUEHPE/AMEMBASSY LIMA PRIORITY 4792
RUEHMN/AMEMBASSY MONTEVIDEO PRIORITY 3418
RUEHRC/DEPT OF AGRICULTURE WASHDC PRIORITY
RUCPDO/DEPT OF COMMERCE WASHDC PRIORITY

UNCLAS SANTIAGO 002303

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E.O. 12958: N/A
TAGS: [ETRD](#) [KIPR](#) [PREL](#) [CI](#)
SUBJECT: CHILE'S SPECIAL 301 OUT-OF-CYCLE REVIEW: POST
RECOMMENDS PRIORITY WATCH LIST

REF: A. STATE 149667

[1](#)B. SANTIAGO 1761

[1](#)1. (SBU) Summary: Post recommends that Chile be placed on the Special 301 Priority Watch List. Nearly three years after the entry into force of the U.S.-Chile Free Trade Agreement, the GOC's institutional framework and political commitment to IPR protection, whether for pharmaceutical patents or copyrighted material, remain unclear at best. Over the last five months since the announcement of an Out-Of-Cycle Review for Chile, the USG has made a concerted effort to understand better what progress Chile might have made on IPR issues. Even during the Santiago visit of A/USTR Eissenstat, the GOC was unable to lay out in an understandable fashion its IPR protection regime. Though clear the GOC has taken some steps over the last several years, real progress remains slow and spotty at best. Worse, there seems to have been no increase in the GOC's political commitment to protecting IPR, even for its own long-term development. It is time to recognize that the emperor has no clothes and place Chile on the Priority Watch List. End Summary.

Data Protection

[1](#)2. (SBU) As reported in ref B, the GOC appears to have made some progress in providing data protection for innovative pharmaceuticals. The GOC holds out Decree 153, published in December 2005, as a major step forward in providing protection. At least one innovative drug has been granted data protection for its clinical trials under this decree. That being said, the decree creates many technical barriers to receiving protection. Whether the decree will be applied realistically and consistently by the Ministry of Health and the Instituto de Salud Publica (ISP is the rough equivalent of the FDA) remains a large question mark.

Pharmaceutical Patent Violations) No Linkage In Sight

[1](#)3. (SBU) On the main issue of patent violations, the continued absence of any linkage between the granting of

marketing rights and the existence of valid patents, there has been no progress. The GOC privately admits that valid patents have been violated in the past but maintains this will not happen again. However, it is unable to explain to the USG or to the affected pharmaceutical companies how it will be able to ensure these patents are not violated. In response to the question of the best course of action should a patent be violated now or in the future, the GOC's only suggestion is for companies to turn to the court system. It considers the existing court system to be the linkage required under the FTA. In essence, the GOC has shifted the burden of upholding existing valid patents from itself to the patent holder and by extension to an unprepared court system.

¶4. (SBU) The GOC maintains that patent rights must be upheld by court rulings, rather than by executive branch decisions on the part of either the ISP or the patent office. It is possible that Chile's new patent regulations might expedite the issuance of civil injunctions to stop the marketing of unauthorized copies. However, it is too early to tell how or even if this procedure will work. What is clear is that the GOC intends to put the administrative and financial burden wholly on the original patent holder to defend its patent rights in Chile. The capacity of the Chilean court system and its judges to serve as effective enforcers of patent rights remains questionable at best.

Word Games

¶5. (SBU) In its discussion with A/USTR Eissenstat in August, the GOC played semantics by arguing that the ISP's issuance of sanitary approval does not violate the FTA's provision, which bars Chile from granting marketing approval in violation of a patent holder's rights, because the ISP does

not literally grant "marketing approval." But the fact is, once a product receives sanitary approval, it can be legally sold in Chile. This intentional failure to link the sanitary approval process to existing, valid patent rights means quite simply that pirated copies of patented medicines are able to reach the Chilean market legally.

¶6. (SBU) The FTA specifies in Article 17.10.2 that parties "shall not grant marketing approval to any third party prior to the expiration of the patent term." When pushed, the GOC's official position is that sanitary approval is not marketing approval. However, there is no entity in the Chilean Government which issues marketing approval and the concept itself does not exist in the GOC approval process for any product. In essence, the ISP's granting of sanitary approval is official GOC approval to allow a pharmaceutical product to come to market.

Inadequate Copyright Anti-Piracy Efforts

¶7. (SBU) On the streets of Chile's major cities and at informal flea markets, the Chilean police can be relatively aggressive in arresting sellers of pirated optical media. However, these efforts have little long-term impact as punishment is minimal, with most IPR violators not even paying fines and criminal penalties suspended. The police rarely investigate the manufacturing and distribution of pirated materials. As a consequence, U.S. content industries report that piracy in Chile continues to cost U.S. companies significant revenue and market share in music, movies and software.

¶8. (SBU) An anti-piracy bill introduced in early 2004 remains in the Chilean Congress pending further review. Most local and international industry observers consider the bill's civil and criminal penalties too low to serve as an effective deterrent. On another front, the GOC has also been slow in seeking to obtain legitimate copies of computer software for use by all government ministries, as required by the U.S.-Chile FTA. President Lagos issued an executive order in 2003 instructing government offices to procure only licensed

software, but there has been no formal follow-up. The weak anti-piracy bill combined with the GOC's half-hearted attempt to police its own use of pirated software does not speak well of the Chilean Government's commitment to copyright protection.

Recommendation: Place Chile on the Priority Watch List

¶9. (SBU) At the heart of the lack of progress on IPR protection in Chile is a lack of political will. Chilean policy decisions and actions continue to fall short of official rhetoric and formal trade agreement commitments on IPR. It is possible that placing Chile on the Priority Watch List -- it would become the first U.S. FTA partner to become a PWL country -- will initiate a needed public debate on the value of IPR to Chile. It will certainly be seen by Chile as punishment should Chile vote for Venezuela for a non-permanent UNSC seat. Nonetheless, the facts speak for themselves.

¶10. (SBU) One of the pillars of President Bachelet's future vision for Chile is innovation. That vision remains largely unarticulated, but clearly investment in and protection of intellectual property rights could play a constructive role in fostering innovation. It is time for Chile to put some consistent and transparent substance behind its rhetoric. While the GOC provides assurances it understands USG concerns on patents and copyrights, and it claims it has been moving to address them (and constantly seeks praise for the steps it has taken), real progress on the ground has been minimal. Post has a strong sense that the GOC will continue, as long as it feels it can get away with it, to do the minimum to keep the U.S. at bay. At this point we have no choice but to recommend Chile be placed on the Priority Watch List.

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